At the meeting of the Technical Electronic Products Radiation Safety Standards Committee on April 8 and 9, 1997, staff of the CDRH will discuss with the Committee concepts for proposed amendments to the performance standard for diagnostic x-ray systems which address fluoroscopic x-ray systems. The topics under consideration for possible amendments are described below. There will be limited opportunity for comments from the public on these topics at the advisory committee meeting. Individuals wishing to provide comments or make statements in person at the meeting should contact the Executive Secretary for the Committee, Dr. Orhan Suleiman (Telephone 301-594-3533, FAX 301-594-3306) before March 28, 1997.

CDRH is proposing the development of amendments to the Performance Standard for Diagnostic X-ray Systems and their Major Components (21 CFR 1020.30 - 1020.33) to address changes in the technology and clinical application of fluoroscopic x-ray systems. These topics are listed below followed by a brief description of the nature of the proposed topic.

Topics for which amendments are proposed and the affected sections of 21 CFR 1020.30 - 1020.33

1. Conversion to SI quantities and units.

2. Clarification of applicability of requirements to digital fluoroscopy systems.

3. 1020.30(h) Amendment to incorporate draft Compliance Policy Guide on Information to be Provided to Users.

4. 1020.30(m) Requirement for increased HVL.

5. 1020.32(b)(2)(v) Requirement for improved x-ray field limitation.

6. 1020.32(g) Clarification on minimum source-to-skin distance for mini-C-arm systems.

7. 1020.32(h) Requirement for indication of cumulative fluoroscopic exposure time.

8. 1020.32(j) Requirement for means to provide "last-image-hold" feature.

9. 1020.32(k) Requirement for indication of air kerma rate and cumulative air kerma.

1. Change to SI quantities and units

This proposal is to amend all sections of the performance standard for diagnostic x-ray systems to use the radiation quantity "air kerma" in place of the quantity "exposure" and to change the units to SI units.

2. Clarification of applicability of requirements to digital fluoroscopy systems.

The current organization and structure of the standard, which assumes the presence of an x-ray image intensifier as the basis for many of the requirements, may be inappropriate for digital fluoroscopy systems. These systems use digital means to perform both radioscopy and radiography (using the IEC definitions of these terms). Such systems may not have an image intensifier tube in the future, and they may use other devices as the image receptor. The structure and organization of the standard may need revision with the aim of dealing with these developments and to be consistent with the IEC terminology.

3. Amendment to incorporate draft Compliance Policy Guide on information to be provided to users.

This proposal would amend the requirements on the content of information which must be provided to users to include specific information on the air kerma rate for certain modes of operation. This amendment will incorporate into the standard a draft Compliance Policy Guide which has been developed, but not yet issued, and is intended to interpret section 1020.30(h) for certain "unique" modes of fluoroscopic system operation.

4. Amendment to add additional requirements for minimum half-value layer for systems designed for interventional radiology.

This proposal will add requirements to increase the minimum half-value layer requirements for fluoroscopic systems designed for interventional radiology. A working definition is that systems which permit the x-ray beam axis to be moved relative to the normal to the table top are assumed to be designed for interventional radiology. Systems in which the x-ray beam direction is fixed with respect to the plane of the tabletop, such as conventional radiographic/fluoroscopic systems would not be included.

5. Amendments to require improved x-ray field limitation.

This proposal is to amend the standard to require improved limitation of the x-ray beam to the actual area of the image receptor being used for image capture and to reduce the amount of nonuseful beam striking the patient.

6. Amendment to clarify the requirements on the minimum source-skin distance for small, mobile or portable "C-arm" fluoroscopic systems.

The purpose of this amendment is to address numerous variances which have been requested and granted for systems which have limited source-image-receptor distances to deviate from the current requirement for the minimum source-skin distance. The amendment is intended to specify the conditions under which a shorter source-skin distance is permitted and to obviate the need for continued variances from the standard.

7. Amendment to require indication of cumulative fluoroscopic exposure time.

The proposed amendment would require the means to indicate the cumulative time of fluoroscopic irradiation of a patient during an examination or procedure.

8. Amendment to require provision of "last image hold" feature on fluoroscopic systems.

This amendment would require that all fluoroscopic x-ray systems be provided with a means to continuously display, following termination of any exposure period, the last image acquired.

9. Amendment to require indication of air kerma rate and cumulative air kerma.

The proposed amendment would require the means to display to the fluoroscopist at the fluoroscopist's working position the cumulative air kerma and the rate (air kerma per unit time) at which air kerma accrues during irradiation of a patient in an examination or procedure.